REMARKS/ARGUMENTS

This Amendment and the following remarks are intended to fully respond to the Office Action mailed May 26, 2006. In that Office Action, claims 1-18 were examined, and all claims were rejected. More specifically, claims 1-4, 6, 7 and 9 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Wheeldon et al. (USPN 4,670,007); claims 10-13, 15, 16, and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wheeldon; and claims 5, 8, 14, and 17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wheeldon. Reconsideration of these rejections, as they might apply to the original and amended claims in view of these remarks, is respectfully requested.

In this Response, claims 1 and 10 have been amended. No claims have been canceled or newly added. Therefore, claims 1-18 remain present for examination.

The claims in the present application are directed to systems and methods of accurately and rapidly delivering sterile fluids for use in a cosmetic surgery procedure, such as lipoplasty or filling of saline breast implants. These claimed systems are significantly different than systems used for intravenous (IV) delivery of fluids to a patient. The present application makes a clear distinction between the two types of fluid delivery systems, and notes several reasons why systems for IV delivery of fluids are not suitable for use in surgical procedures requiring rapid delivery of fluids. For example on page 2, line 20-page 3, line 2, the specification describes several problems with the use of IV systems for rapid delivery of fluids in surgical procedures. Some of the noted problems with using IV systems include that they are too slow, and they do not provide sufficient pressure to infuse fatty tissues, as would be necessary in lipoplasty. *See Specification*, page 2, line 20-page 3, line 2. As a consequence, the use of an IV system to deliver fluids for surgical procedures requiring rapid delivery of fluids would result in unduly prolonged operations and undue patient trauma. *See Id.* For at least these reasons, someone of ordinary skill in the art trying to develop a system for rapid delivery of sterile fluids for surgical procedures would not look to IV systems to solve problems encountered in rapid delivery of fluids. Below, Applicant addresses more specifically, the rejections in the Office Action.

Claim Rejections – 35 U.S.C. § 102

Claims 1-4, 6, 7, and 9 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Wheeldon et al. (USPN 4,670,007) hereinafter "Wheeldon." Applicant respectfully traverses this rejection.

The Office Action asserts that Wheeldon discloses all the elements of the claims. In making this assertion, the Office Action states "the device is capable of being used during any type of surgical procedure that would require IV administration of fluids including a cosmetic procedure such as lipoplasty." *Office Action* (5/26/06), page 2. The Office Action goes on to state that "[t]he speed control is considered capable of delivery of fluid within any range set by the user including 30 ml/min to 1000 ml/min." *Office Action* (5/26/06), page 2. Applicant respectfully disagrees with the assertions made in the Office Action.

The legal standard applied to rejections under 35 U.S.C. § 102 is that a claim is anticipated only if each and every element as set forth in the claim is found, expressly or inherently described, in a single prior art reference. *See Manual of Patent Examining Procedure (MPEP)* § 2131 (*citing Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 Fed. Cir. 1987)). The identical invention must be shown in as complete detail as is contained in the claim. *See Id.* (*citing Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)).

As described above, those of skill in the art would recognize that the considerations that are applicable to intravenous delivery of fluids are not the same as rapidly delivering fluid in a cosmetic surgery procedure, such as may be performed in lipoplasty or filling of saline breast implants. The flow rates are dramatically different. In Appendix A, Applicant has enclosed information that describes typical flow rates used in IV systems. Specifically, the information includes:

- JL Demoruelle and WL Harrison, Flow Rate Maintenance and Output of Intravenous Fluid Administration Sets, American Journal of Hospital Pharmacy, vol. 32, issue 2, Abstract, 1975.
- RD Leff and RJ Roberts, Effect of Intravenous Fluid and Drug Solution Coadministration on Final-Infusate Osmolality, Specific Gravity, and pH, American Journal of Hospital Pharmacy, vol. 39, issue 3, Abstract, 1982.

- Description of FLO-GARD Volumetric Infusion Pumps (Industry Standard) from Baxter Website (http://www.baxter.com/products/medication_management/infusion_pumps/large_volume_infusion_pumps/flo_gard/index.html), accessed September 26, 2006.

As the references indicate, intravenous fluids are most often delivered at rates in the range of 0.08 ml/min (5 ml/hr) to 2.5 ml/min (150 ml/hr), whereas claim 1 of the instant invention is directed to rates of 30 ml/min to 1000 ml/min. This is a factor of 375 on the low end and a factor of 400 on the upper end, clearly showing the significant difference in flow rates.

Turning now to the specific rejection of claim 1, Applicant politely submits that Wheeldon does not anticipate the claims, because it fails to teach or suggest all the elements of the claims, and specifically fails to disclose a fluid flow rate within a range of 30 ml/min to 1000 ml/min. It appears as if the Office Action assumes that Wheeldon inherently teaches this element. *See Office Action* (5/26/06), page 2 ("[t]he speed control is considered capable of delivery of fluid within any range set by the user including 30 ml/min to 1000 ml/min."). Although the inherent disclosures of a reference may be used to show anticipation of a claim, to establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' MPEP § 2112 (*quoting In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (emphasis added)). To establish inherency, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." MPEP § 2112 (*quoting Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)).

Applicant kindly submits that the Office Action has not made the requisite showing to establish that Wheeldon discloses a fluid flow rate of 30 ml/min to 1000 ml/min. The Office Action does not provide any line of reasoning or basis in fact to show that the system of Wheeldon ***necessarily*** is capable of delivering fluid at flow rates of 30 ml/min to 1000 ml/min.

Applicant submits that the system of Wheeldon could not possibly have fluid flow rates as high as the claimed range. As those with ordinary skill in the art would understand, intravenous delivery of fluids occurs at low flow rates as indicated previously. Indeed, even Wheeldon itself indicates that its system operates at rates measured by "ml/hr." *See Wheeldon*, col. 6, lines 61-64. As the references cited in Appendix A illustrate, intravenous systems with flow rates in the range of 1,800 ml/hr (30 ml/min) to 60,000 ml/hr (1000 ml/min) would be at best very unlikely, and certainly unlikely to meet the burden required for establishing inherency. Accordingly, the Examiner has not met the burden of establishing the flow rates through inherency.

Further, independent claim 1 is being amended to clarify that the claim is directed to a system that accurately ***and rapidly*** delivers sterile fluids for use in cosmetic surgery. This Amendment highlights an important difference between the claimed invention and systems such as those of Wheeldon, namely the ability to rapidly deliver fluids. Although the amendment is being made to the preamble, "if the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *MPEP* § 2111.02 (*quoting Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999)). Claim 1 relies on the preamble for antecedent basis, e.g. "surgical procedure," and therefore should be construed to limit the claim. Amended claim 1, therefore, is further distinct from Wheeldon, because Wheeldon does not teach or suggest "a system for accurately ***and rapidly*** delivering sterile fluids for use in a cosmetic surgery procedure" as recited in claim 1.

For at least these reasons, claim 1 is patentable over the disclosures of Wheeldon. Claims 2-9 depend upon claim 1 and are allowable for at least the same reasons.

Claim Rejections – 35 U.S.C. § 103

Claims 10-13, 15, 16, and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wheeldon. Applicant traverses this rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to

combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See *MPEP* § 706.02(j) (*citing In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)). The Applicant respectfully submits that the Office Action does not meet the burden of establishing a *prima facie* case of obviousness, because Wheeldon does not disclose all the elements of the currently pending claims and the Office Action does not cite to any other references that compensate for the deficiency in Wheeldon. Moreover, the Office Action does not provide adequate motivation for someone of ordinary skill in the art to modify the system of Wheeldon to include the claimed flow rate range.

Similar to claim 1, independent claim 10 recites, *inter alia*, a fluid flow rate of 30 ml/min to 1000 ml/min and has also been amended to recite "rapidly." As described above with respect to claim 1, Wheeldon does not teach or suggest these limitations, and the Office Action fails to cite other references to compensate for this deficiency. Thus, the Examiner has not established a *prima facie* case of obvious for rejecting claim 10. Claims 11-18 depend upon claim 10 and are allowable for at least the same reasons.

Moreover, Applicant kindly submits that the Office Action does not provide adequate motivation for modifying the system of Wheeldon to deliver fluid within a range of 30 ml/min to 1000 ml/min. As described above, Wheeldon is directed at intravenous delivery of fluids, which must occur at significantly lower flow rates than the claimed range of the instant invention. Accordingly, modifying the system of Wheeldon to deliver fluids at flow rates within 30 ml/min to 1000 ml/min, as suggested in the Office Action, would make the system unsuitable for its intended purpose, i.e., intravenous fluid delivery. This is further supported by the references in Appendix A, which describe the very slow flow rates required for IV delivery of fluids. If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, ***then there is no suggestion or motivation to make the proposed modification***. *See MPEP* § 2143.01 (*quoting In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) (emphasis added). For this additional reason, the Office Action has not established a *prima facie* case of obviousness with respect to claims 10-18.

Finally, in rejecting claims 5, 8, 14, and 17 the Office Action asserts that the "Applicant has not disclosed that PVC solves a problem, is used for a particular purpose or provides an advantage." *Office Action* (5/26/06), page 2. Applicant respectfully disagrees. As stated in

various portions of the patent application, one feature of some embodiments of the present invention is the elimination of distention caused by the pressure generated by the pump system. *See Application*, page 4, lines 22-24 and page 8, lines 3-10. As stated on page 8, lines 3-10 the use of PVC in appropriate thicknesses achieves the benefits of eliminating distention. Nevertheless, claims 5, 8, 14, and 17 are dependent upon one of claims 1 or 11 and are allowable for at least the same reasons.

Conclusion

This Amendment fully responds to the Office Action mailed on May 26, 2006. Still, the Office Action may contain arguments and rejections that are not directly addressed by this Amendment because they are rendered moot in light of the preceding arguments in favor of patentability. Hence, failure of this Amendment to directly address an argument raised in the Office Action should not be taken as an indication that the Applicant believes the argument has merit. Additionally, failure to address statements/comments made in the Office Action does not mean that the Applicant acquiesces to such statements or comments. Furthermore, the claims of the present application may include other elements, not discussed in this Amendment, which are not shown, taught, or otherwise suggested by the art of record. Accordingly, the preceding arguments in favor of patentability are advanced without prejudice to other bases of patentability. It is believed that no fees are due with this Amendment. However, the Commissioner is hereby authorized to charge any deficiencies or credit any overpayment with respect to this patent application to deposit account number 13-2725.

In light of the above remarks and amendments, it is believed that the application is now in condition for allowance and such action is respectfully requested. Should any additional issues need to be resolved, the Examiner is requested to telephone the undersigned to attempt to resolve those issues.

In light of the above remarks and amendments, it is believed that the application is now in condition for allowance and such action is respectfully requested. Should any additional issues need to be resolved, the Examiner is requested to telephone the undersigned to attempt to resolve those issues.

Respectfully submitted,

Dated: September 26, 2006

Rene' A. Perdyra, Reg. No. 45,800
MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, MN 55402-0903
303.357.1637

23552
PATENT TRADEMARK OFFICE